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EXHIBIT 2

Livingston Products, Inc.
260 Holbrook Drive
Wheeling, IL 60090
Phone 847-808-0900
Fax 847-808-0904
Contact: Troy Livingston, President

September 18, 2003

510(k) Summary

1. Identification of the Device:
   Proprietary-Trade Name: Advantage Breast Compression paddle
   Classification Name: IZH
   Common/Usual Name: Breast Compression Paddle

2. Equivalent legally marketed device: This product is similar in design and identical in. function to the S.O.F.T. Paddle, American Mammographics, Inc, K023229

3. Indications for Use (intended use) For use in Screening Mammographic Imaging as a Specialty Paddle for Full Breast Compression as an alternative to conventional breast compression paddles..

4. Description of the Device: The Advantage paddle is a breast compression paddle comprising of a rectangular tray-like structure of an FDA approved biocompatible material (Eastman Kodak PETG Copolyester #6763). The paddle has a flat section and a tilted section made possible by two-section construction. The first section of the paddle is foamed rigidly and is positioned near the patient's chest and extends about one inch away from the chest. In operation, this provides a vertically oriented force to the breast that tends to keep the breast tissue from being forced into the chest wall and provides a clearer film of the breast tissue adjacent the chest. The second section is formed and structured to flex for the purpose of tilting the paddle downward to compress the nipple end of the breast in a steady position as the X-ray is taken. The "Advantage" paddle is meant for use with an 18 x 24cm bucky. That is a standard size used in the industry

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5. Safety and Effectiveness, comparison to predicate device: Comparison of construction materials, durability testing, and examination of images taken during use of the device reveals the Advantage Paddle is as safe and effective ad the predicate device.

Comparison Areas	S.O.F.T. Paddle, American Mammographics, Inc, K023229	Livingston Products Advantage Paddle
Indications for use	For use in Screening Mammographic Imaging as a Specialty Paddle for Full Breast Compression as an alternative to conventional breast compression paddles	SAME
Materials	LEXAN, a GE product Polycarbonate plastic and steel	KODAR PETG Copolyester and steel, essentially the SAME.
Where used	Mammography procedures	SAME
Reason for use over conventional paddles	Improved patient comfort and better images	SAME

6. Conclusion: In all important respects, the Advantage Breast Compression Paddle is substantially equivalent to the S.O.F.T. Paddle, American Mammographics, Inc, K023229

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2003

Livingston Products, Inc.
c/o Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K033202
Trade/Device Name: Advantage Breast Compression Paddle
Regulation Number: 21 CFR §892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: September 30, 2003
Received: October 2, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K033202

Device Name: Advantage Breast Compression Paddle.

Indications for Use: For use in Screening Mammographic Imaging as a Specialty Paddle for Full Breast Compression as an alternative to conventional breast compression paddles.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033202